

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

GILEAD SCIENCES, INC., *et al.*,

Plaintiffs,

v.

SAFE CHAIN SOLUTIONS, LLC, *et al.*,

Defendants.

**Civil Action No. 21-cv-4106
(AMD)(RER)**

ECF CASE

**MEMORANDUM OF LAW IN SUPPORT OF SCRIPTS WHOLESALE INC.'S
MOTION TO VACATE OR AMEND THE ASSET FREEZE ORDER**

Richard S. Schurin
Stanley R. Goodman
Steven Stern
Moshe Y. Allweiss
STERN & SCHURIN LLP
Attorneys for Defendants
Scripts Wholesale, Inc.

Dated: January 20, 2022
Garden City, New York

TABLE OF CONTENTS

| | |
|---|-----|
| TABLE OF AUTHORITIES | iii |
| INTRODUCTION | 1 |
| STATEMENT OF FACTS | 5 |
| ARGUMENT | 6 |
| I. THE BURDEN OF PROOF IS ON GILEAD TO MAINTAIN THE <i>EX PARTE</i> ASSET FREEZE AGAINST SCRIPTS..... | 6 |
| II. GILEAD’S APPLICATION FOR AN <i>EX PARTE</i> ASSET FREEZE ORDER INDISCRIMINATELY LUMPED SCRIPTS WITH THE OTHER DEFENDANTS | 9 |
| III. GILEAD’S CLAIM OF COUNTERFEITING AGAINST SCRIPTS IS LIKELY SUBJECT TO DISMISSAL FOR FAILURE TO STATE A PLAUSIBLE CLAIM | 11 |
| A. Gilead’s Claim for Counterfeiting Based on False Pedigrees Is Precluded Under DSCSA, 21 U.S.C. § 360eee to 360eee-4 and Renders the Case Subject to Dismissal for Failure to State a Claim | 11 |
| B. Gilead Cannot Assert a Plausible Claim for Counterfeiting Based Upon a Suspect Pedigree | 13 |
| C. The Two (2) Prior Instances of Tampering and Adulteration Cited in the Second Amended Complaint Do Not Support the Asset Freeze Order | 19 |
| IV. GILEAD HAS NOT DEMONSTRATED THAT SCRIPTS WILL DISSIPATE OR SECRETE ITS ASSETS | 19 |
| V. THE PUBLIC INTEREST IS NOT SERVED BY MAINTAINING AN ASSET FREEZE OF SCRIPTS’ FUNDS | 22 |
| CONCLUSION..... | 22 |

TABLE OF AUTHORITIES

Cases

| | |
|--|--------|
| <i>Adelphia Communs Corp. v. Rigas (In re Adelphia Communs. Corp.),</i> 2004 U.S. Dist. LEXIS 19478 (S.D.N.Y. 2004) | 22 |
| <i>Amarin Pharma, Inc v. ITC,</i> 923 F.3d. 959 (Fed. Cir. 2019) | 12, 13 |
| <i>Bell & Howell: Mamiya Co. v. Masel Supply Co.,</i> 719 F.2d 42 (2d Cir. 1983) | 15 |
| <i>BMaddox Enters., LLC v. Oskouie,</i> 2017 U.S. Dist. LEXIS 146766 (S.D.N.Y. 2017) | 7, 21 |
| <i>Cartier Int'l B.V. v. Liu</i> , No. 02 Civ. 7926 (TPG), 2003 U.S. Dist. LEXIS 6381, 2003 WL 1900852 (S.D.N.Y. Apr. 17, 2003) | 7 |
| <i>Citibank N.A. v. Citytrust,</i> 756 F.2d 273 (2d Cir. 1985) | 19 |
| <i>Coty, Inc v. Cosmopolitan Cosmetics, Inc.,</i> 432 F. Supp. 3d 345 (S.D.N.Y. 2020) | 18 |
| <i>Dong v. Miller,</i> 2018 U.S. Dist. LEXIS 48506 (E.D.N.Y. 2018) | 1 |
| <i>General Electric Company v. Speicher,</i> 877 F.2d 531 (7th Cir. 1989) | 16 |
| <i>Grupo Mexicano v. Alliance Bond Fund,</i> 527 U.S. 308, 144 L.Ed. 2d 319, 119 S.Ct. 1961 (1999) | 1, 13 |
| <i>Gucci Am. v. Bank of China,</i> 768 F.3d 122 (2d Cir. 2014) | 8 |
| <i>Gucci Am., Inc. v. Guess?, Inc.,</i> 868 F. Supp. 2d 207 (S.D.N.Y. 2012) | 14 |
| <i>Haggiag v. Brown,</i> 728 F. Supp. 286 (S.D.N.Y. 1990) | 21 |
| <i>In re Valsartan, Losartan & Irbesartan Prods. Liab. Litig.,</i> 2020 U.S. Dist. LEXIS 238919 (D.N.J. 2020) | 12 |

| | |
|---|---------|
| <i>Innovation Ventures, LLC v. Pittsburgh Wholesale Grocers, Inc.</i> , 2012 U.S. Dist. LEXIS 181590 (N.D. Ca. 2012) | 10 |
| <i>Kebapci v. Tune Core Inc.</i> , 2016 U.S. Dist. LEXIS 159054 (E.D.N.Y. 2016) | 20 |
| <i>Matrix Distribs. v. N.A. of Bds. of Pharm.</i> , 2020 U.S. Dist. LEXIS 228271 (D.N.J. December 4, 2020) | 12 |
| <i>MyWebGrocer, LLC v. Hometown Info, Inc.</i> , 375 F.3d 190 (2d Cir. 2004) | 8 |
| <i>N. Face Apparel Corp. v. TC Fashions, Inc.</i> , 2006 U.S. Dist. LEXIS 14226, 2006 WL 838993 (S.D.N.Y. Mar. 30, 2006) | 7 |
| <i>Spin Master v. Aciper</i> , 2020 US Dist. LEXIS 206278 (S.D.N.Y. 2020) | 1, 7, 8 |
| <i>Sterling Ornaments Pvt. Ltd. v. Hazel Jewelry Corp.</i> , 2015 U.S. Dist. LEXIS 77331 (S.D.N.Y. 2015) | 19-20 |
| <i>United States v. Hanafy</i> , 302 F.3d 485 (5th Cir. 2002) | 17 |

Statutes

| | |
|---------------------------------------|--------|
| 15 U.S.C. § 1116(d) | 14, 15 |
| 15 U.S.C. § 1117(b) | 14 |
| 15 U.S.C. § 1127 | 14, 15 |
| 15 U.S.C. § 1051 <i>et seq.</i> | 1 |
| 21 U.S.C. §§ 360eee to 360eee-4..... | 2, 11 |
| 21 U.S.C. § 360eee-4(b)(1) | 12 |

Other Authorities

| | |
|--|-------|
| 130 Cong. Rec. H12076 (daily ed. Oct. 10, 1984)..... | 15 |
| Black’s Law Dictionary (10th ed. 2014) | 14-15 |
| J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition, § 25:10 | 14 |

| | |
|---|----|
| J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition, Appendix A8 (5th ed.) | 15 |
|---|----|

INTRODUCTION

Defendant Scripts Wholesale, Inc. (“Scripts”) moves this Court to vacate or otherwise modify the *ex parte* Asset Freeze Order entered against it on October 16, 2021. (Schurin Decl., Ex. A) The Asset Freeze Order against Scripts is predicated upon Gilead’s allegations of counterfeiting under the Lanham Act, 15 U.S.C. § 1051 *et seq.*

For over a decade, Scripts has been an established and reputable wholesale distributor of pharmaceutical drugs. Scripts is licensed in more than thirty (30) states. Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC and Gilead Sciences LLC (collectively “Gilead”) have frozen Scripts’ assets in the amount of \$5,641,489.01, which is essentially all of Scripts working capital that it desperately needs to both continue its business and to defend itself against Gilead’s claims in this litigation. These funds are in addition to the actual pharmaceutical products that Gilead has seized from Scripts, which are also valued at more than \$5 million. Since the asset freeze was ordered, Scripts’ business has been severely hampered.

The *ex parte* Asset Freeze Order against Scripts must be vacated or significantly modified since Gilead does not meet the standards necessary to uphold and maintain the freeze of Scripts’ bank accounts. A pre-judgment asset freeze is a “dramatic and extreme” provisional remedy that cannot be justified against Scripts in this case where the claims asserted against Scripts by Gilead are severely flawed and there is no evidence that Scripts will dissipate its assets. *See e.g., Grupo Mexicano v. Alliance Bond Fund*, 527 U.S. 308, 144 L.Ed. 2d 319, 119 S.Ct. 1961 (1999). Indeed, “[a] Court may not enter a preliminary injunction simply to safeguard [a defendant’s] assets in the event that [defendant is] ultimately held liable on these claims.” *Spin Master v. Aciper*, 2020 US Dist. LEXIS 206278, at *8 (S.D.N.Y. 2020) *citing Dong v. Miller*, 2018 U.S. Dist. LEXIS 48506, at *9 (E.D.N.Y. 2018).

An asset freeze should only be ordered and maintained when (1) the liability for counterfeiting against a defendant is certain, and (2) there is a significant risk that the assets which are frozen would dissipate or be secreted, thus rendering enforcement of a judgment impossible. Neither certain liability for counterfeiting nor concerns for the dissipation of Scripts' assets exists here. Therefore, the asset freeze must be vacated by the Court.

The Asset Freeze Order must be vacated because Gilead's claims for counterfeiting against Scripts will likely fail, as a matter of law, for two distinct reasons. First, Gilead's counterfeiting claim against Scripts, which is premised upon false pedigree documents, may be adjudicated solely by the Food and Drug Administration (hereinafter "FDA") under the Drug Supply Chain Security Act (hereinafter "DSCSA"), 21 U.S.C. §§ 360eee to 360eee-4. Notably, there is no private right of action under DSCSA under which Gilead may assert the type of claim based on a false pedigree that Gilead now asserts against Scripts in this case.

In particular, DSCSA aims to regulate the drug supply chain by implementing a uniform system to trace and verify the identity of a drug as it passes through the supply chain. To this particular end, DSCSA provides requirements and a regulatory framework for dealing with incorrect pedigrees/T3s which the FDA deems "suspect." Accordingly, Gilead's independent designation of pedigrees/T3s as counterfeit attempts to divest the FDA from being the sole arbiter of pedigrees/T3s under the regulatory framework set forth in DSCSA. DSCSA also does not delegate a private right of action to private entities, such as Gilead, for violations under DSCSA. Likewise, violations of DSCSA may not be cloaked in terms of the Lanham Act to give private entities a private right of action, since doing so would impermissibly shoehorn questions of regulatory compliance and enforcement – which fall exclusively under the purview of the FDA – into the Lanham Act.

Second, Gilead's claims for counterfeiting against Scripts based on Scripts' alleged use of false pedigrees/T3s will likely fail since it is premised upon a novel and flawed theory of counterfeiting under the Lanham Act. Gilead's counterfeiting claim is flawed primarily because the allegedly false pedigrees/T3s relate to genuine pharmaceutical products that are indisputably manufactured by Gilead. Thus, Gilead's counterfeiting claim involves Scripts' purchase, advertising and sale of genuine and authentic Gilead pharmaceuticals in authentic and genuine Gilead packaging, which cannot sustain the Asset Freeze Order that Gilead acquired against Scripts on an *ex parte* basis.

Since Gilead's counterfeiting claim against Scripts is based upon a flawed theory of liability, Gilead can hardly contend that liability against Scripts for counterfeiting has been firmly established. Indeed, there is not a single reported case that has held that a bottle of pills is counterfeit under the Lanham Act merely because its pedigree is incorrect or "suspect."

With regard to the second requirement for ordering an asset freeze, i.e., dissipation of assets, there are no facts which would establish that Scripts would dissipate or secrete its assets. Scripts has been a responsible and stable business for over a decade. Scripts is licensed in over thirty (30) states. Scripts business is heavily regulated and never once has Scripts been the subject of any disciplinary action. Scripts has always cooperated with Gilead and the FDA in the past. Gilead and its counsel also knew that Scripts was represented by counsel and the identity of that counsel since the start of this case. Based on these facts alone, the Asset Freeze Order entered against Scripts should be vacated in its entirety.

Notably, Gilead's own allegations undermine any notion that Scripts will disappear or dissipate its assets if it is able to recover its now-frozen funds. Scripts is identified as a "new Distributor Defendant" in Gilead's Second Amended Complaint (hereinafter "SAC"). Nearly the

entirety of Gilead's SAC addresses facts and circumstances relating to Scripts' co-defendants which Gilead identifies as the "Leader Defendants," "Supplier Defendants," Marketer Defendants" and "Asset Holder Defendants." Each of these groups of co-defendants is alleged to have conspired with one another to commit the alleged counterfeiting activities described in the SAC. Gilead also asserts claims for RICO violations against these defendants. However, Gilead does not assert its RICO claims against Scripts, nor can it do so, since Scripts was nothing more than an innocent purchaser and distributor of the pharmaceuticals at issue. Yet, despite the clear distinction between Scripts and the other culpable groups of Defendants, Scripts was indiscriminately lumped with the worst actors when Gilead sought extreme preliminary relief.

Finally, since Scripts can neither continue to run its business nor defend itself in this litigation without access to the monies that Gilead has frozen, the balance of the hardships greatly favors vacating (or substantially modifying) the Asset Freeze Order. Since the Asset Freeze Order was granted *ex parte*, Scripts has not yet had the opportunity to respond to the substance of Gilead's claims. Nevertheless, if substantial relief is not granted in the near future, Scripts will be forced out of business. In addition, if the funds which have been frozen on the basis of the *ex parte* Asset Freeze Order are not released, Scripts will also be deprived of the means to defend itself in this costly civil action – a particularly severe result, which would be grossly unfair to Scripts. If the Asset Freeze Order is not vacated (or substantially decreased), the Court would be effectively granting Gilead a victory by depriving Scripts of the means to defend itself.

STATEMENT OF FACTS

Scripts incorporates herein the declarations of Steven Diamantstein (“Diamantstein Decl.”) and Richard Schurin (“Schurin Decl.”) and Exhibits A through H attached to these declarations. Scripts will only restate the relevant highlights.

1. Scripts is an established business licensed in more than thirty (30) states that has never had a license revoked or been the subject of disciplinary action.

Scripts started in business in 2009. (Diamantstein Decl., ¶ 2) Presently, Scripts is licensed to sell pharmaceutical products in more than thirty (30) states. (Diamantstein Decl., ¶ 4, Exhibit H) During all of this time, no state licensing authority has ever revoked or taken disciplinary action against Scripts. (Diamantstein Decl., ¶ 6)

2. Scripts is a stable local business.

There is no legitimate risk that Scripts will depart the jurisdiction. In the twelve (12) years since it opened its doors, Scripts has operated on the third floor of the same building, which also happens to be the location of Mr. Diamantstein’s father’s ground floor retail pharmacy, Lieb Pharmacy. (Diamantstein Decl., ¶¶ 11-12) Steven Diamantstein has lived in Brooklyn his entire life and currently resides in Brooklyn with his wife and two young children. (Diamantstein Decl., ¶¶ 14-15) The Diamantstein family has owned and operated Lieb pharmacy for more than thirty-five (35) years since April 1986. (Diamantstein Decl., ¶ 13) Mr. Diamantstein has no intention of moving his business outside of Brooklyn. (Diamantstein Decl., ¶ 16) All of these indisputable facts establish that Scripts is unlikely to dissipate its assets or evade a valid judgment entered against it.

3. Scripts has maintained its financial assets at a local branch of Chase bank since 2012

For nearly a decade, Scripts has maintained its money in a traditional United States bank located in this jurisdiction. (Diamantstein Decl., ¶¶ 17-18) Scripts has never had a foreign bank

account. (Diamantstein Decl., ¶ 19) There is no evidence to suggest that Scripts is likely to remove its assets from this jurisdiction.

4. Scripts will be unable to continue its business or defend itself in this litigation without access to the money that Gilead has frozen

Scripts desperately needs the funds that have been frozen for the past three months to continue to operate its business as it has prior to the freeze and to defend itself in this extremely costly action. (Diamantstein Decl., ¶¶ 39-47) The cash that Gilead has frozen represents almost all the working capital that Scripts needs to continue its business of buying and selling wholesale pharmaceutical drugs. (Diamantstein Decl., ¶ 39)

With regard to Scripts' defense against Gilead's claims, Scripts is also without the benefit of its insurance coverage. (Schurin Decl., ¶¶ 8-9) After being sued, Scripts tendered Gilead's claims to its insurance carrier, State National Insurance Company, seeking a defense. (Schurin Decl., ¶ 8) On November 8, 2021, State National refused to provide a defense to Scripts, claiming that the suit was not covered because the Second Amended Complaint alleges intentional and willful conduct against Scripts. (Schurin Decl., ¶ 9, Ex. F) If the Court does not vacate the *ex parte* Asset Freeze Order or at least substantially reduce the amount of money that Gilead has frozen, Scripts will be out of business before it has even had a chance to substantively dispute the claims asserted against it.

ARGUMENT

For the following reasons the *ex parte* Asset Freeze Order entered against Scripts was not warranted and should now be vacated or at least substantially reduced.

I. THE BURDEN OF PROOF IS ON GILEAD TO MAINTAIN THE EX PARTE ASSET FREEZE AGAINST SCRIPTS

The Asset Freeze Order against Scripts was entered on an *ex parte* basis, and Scripts has not stipulated to the entry of any preliminary relief. Therefore, the burden remains on Gilead to

prove the continued necessity of the Asset Freeze Order. *See, Spin Master v. Aciper*, 2020 U.S. Dist. LEXIS 206278, *9 (S.D.N.Y. 2020); and *BMaddox Enters., LLC v. Oskouie*, 2017 U.S. Dist. LEXIS 146766, *6 (S.D.N.Y. 2017) (citing cases). This makes sense since Scripts has not yet had the opportunity to contest Gilead's application for the asset freeze, and the Court has not previously made specific findings of fact justifying the asset freeze entered against Scripts.

In *Spin Master*, the procedural facts were similar to those here. The plaintiffs had commenced a lawsuit alleging trademark counterfeiting by filing a complaint under seal and requesting various forms of relief on an *ex parte* basis. At the outset of the case, the court issued a temporary restraining order and directed payment processing providers to freeze defendants' assets contained in any account hosted by the payment providers. *See id.* at *2. The defendant then filed a motion to vacate the *ex parte* relief, including the asset freeze order, and the court was asked to decide whether the defendant's assets should continue to be restrained. *See, id.* at *4. With respect to the burden of proof, the Court explained why plaintiffs still had the burden to prove that maintaining the asset freeze order was necessary. The Court held as follows:

Plaintiffs contend that the burden is on Jscout [defendant] to 'present documentary proof that particular assets are not the proceeds of counterfeiting activities.' (Pls.' Asset Freeze Mem. 3.) However, the cases cited for this proposition involve requests by defendants for relief from asset freezes already imposed by preliminary injunction. *See, N. Face Apparel Corp., 2006 U.S. Dist. LEXIS 14226, 2006 WL 838993, at *3* (where defendant consented to preliminary injunction, and did not appear to dispute the merits of the counterfeit claim but sought for the asset restraints to be 'modified,' burden was on defendant to show that the assets it wanted released were not earned from counterfeiting activities); *Cartier Int'l B.V. v. Liu, No. 02 Civ. 7926(TPG), 2003 U.S. Dist. LEXIS 6381, 2003 WL 1900852, at *1 (S.D.N.Y. Apr. 17, 2003)* (on a motion to vacate a preliminary injunction freezing defendant's assets to release a portion of those assets, defendant bore the burden of showing that a portion of the assets were not the proceeds of counterfeiting activities, in part because the preliminary injunction order contained a provision to that effect). Here, in contrast, the parties have not consented to a preliminary injunction, nor have I made any factual findings or entered an order myself. Rather, what is before me is Plaintiffs'

motion for a preliminary injunction, and they bear the burden of making the requisite showing. *See MyWebGrocer, LLC*, 375 F.3d at 192.

Spin Master v. Aciper, 2020 U.S. Dist. LEXIS 206278, *9-10 (S.D.N.Y. 2020). In order to remove any doubt that the same standard applied in the context of the lifting of an asset freeze, the Court further explained in footnote 8:

Although Plaintiffs addressed the preliminary injunction standard in prior briefing, they do not frame their request for a continuing asset freeze as a motion for a preliminary injunction. Nevertheless, because courts consider prejudgment asset freezes as preliminary injunctions, *see generally, Gucci Am.* 768 F.3d at 130, I apply the preliminary injunction standard to Plaintiff's request.

Id. at *9, n.8.

Similarly, in the instant case, Gilead filed the SAC against Scripts under seal and sought an asset freeze and other preliminary relief on an *ex parte* basis against Scripts that was based solely upon baseless allegations of counterfeiting under the Lanham Act. Since Gilead's requests were made on an *ex parte* basis, Scripts has not yet had the opportunity to contest the merits of Gilead's requests for preliminary relief. Judge Kovner also did not make specific findings of fact against Scripts. Rather, Judge Kovner adopted Gilead's proposed Order, as submitted.

Now, Scripts moves to vacate or modify the Asset Freeze Order, addressing the merits of Gilead's application for the very first time. Accordingly, it would be erroneous and indeed highly prejudicial to now shift to Scripts what should be Gilead's burden of proof to maintain the provisional remedy it received on an *ex parte* basis. As was the case in *Spin Master*, the burden of proof should remain on Gilead to show why the *ex parte* Asset Freeze Order against Scripts must remain in effect and not be vacated or at least substantially reduced.

II. GILEAD’S APPLICATION FOR AN *EX PARTE* ASSET FREEZE ORDER INDISCRIMINATELY LUMPED SCRIPTS WITH THE OTHER DEFENDANTS

In support of its proposed *ex parte* Asset Freeze Order against Scripts, Gilead relied in significant part on the representations contained in the declarations of its trial counsel. (*See*, Schurin Decl., ¶¶ 3-5, Ex. B and Ex. C) Notably, Gilead’s application indiscriminately lumped Scripts in with other co-defendants, even though it was clear from the allegations in the SAC that Scripts took no active part in the actions of the Leader Defendants, the Supplier Defendants, the Marketer Defendants and/or the Asset Holder Defendants. However, in the *ex parte* application, Gilead arbitrarily grouped Scripts in with all of the other co-defendants against which an asset freeze and other preliminary relief were previously successfully sought.

In support of the *ex parte* Asset Freeze Order and other preliminary relief, Gilead’s trial counsel also represented to the Court that he and his firm had substantial experience in counterfeiting cases and that the extraordinary preliminary relief that Gilead was seeking was appropriate and not out of the ordinary. More specifically, in his declarations, Gilead’s trial counsel advised Judge Kovner that the Court could rely on his longstanding reputation and experience having obtained similar type relief in past counterfeiting cases, particularly in the Eastern District of New York. (Schurin Decl., Ex. B, ¶ 3, and Ex. C, ¶¶ 3, 11-15) For example, in his declarations dated October 14, 2021 and July 21, 2021, Gilead’s trial counsel stated that he has “obtained and successfully executed dozens of *ex parte* seizure orders issued in anti-counterfeiting actions throughout the United States, as well as internationally.” (Schurin Decl., Ex. B and Ex. C, ¶ 3) Notably, none of the prior counterfeiting cases cited in his declarations involved the same form of novel claim of counterfeiting that is now asserted against Scripts, which are premised upon incorrect and/or suspect pedigrees.

Gilead's trial counsel further stated that "[n]one of those seizures [in prior cases] has been found to be wrongful or has led to the forfeiture of any portion of the seizure bond." (Schurin Decl., Ex. B. and Ex. C, ¶3) Accordingly, Gilead was representing to the Court that it could trust that Gilead was not seeking *ex parte* relief that was not warranted against Scripts.

Significantly, Gilead's representations to Judge Kovner omitted a material fact that Scripts believes likely would have been relevant to Gilead's application had it been disclosed at the time. In particular, Gilead's trial counsel and one of his clients in a prior counterfeiting case had been criticized in association with a seizure that a court believed extended beyond the scope of what was necessary in that case as to a particular party similarly situated to Scripts. In particular, in *Innovation Ventures, LLC v. Pittsburgh Wholesale Grocers, Inc.*, 2012 U.S. Dist. LEXIS 181590 (N.D. Ca. 2012), District Court Judge William Alsop of the Northern District of California criticized Innovation Ventures for seeking excessive *ex parte* relief against an entity – like Scripts – that was merely a reseller of accused products, and not an intentional infringer.

Just as in *Innovation Ventures*, Scripts, a reseller, was indiscriminately lumped in by Gilead with other co-defendants which are likely deserving of the extraordinary relief sought by Gilead. By the same token, since Scripts innocently participated in the purchase, advertising and sales of the accused products that were associated with the false pedigrees, the extraordinary relief granted to Gilead vis-à-vis other defendants should never have been sought by Gilead against Scripts in the first instance. By Gilead's own pleading, Scripts is not a primary actor in the RICO and Lanham Act conspiracies alleged in the SAC.

III. GILEAD'S CLAIM OF COUNTERFEITING AGAINST SCRIPTS IS LIKELY SUBJECT TO DISMISSAL FOR FAILURE TO STATE A PLAUSIBLE CLAIM

The *ex-parte* Asset Freeze Order entered against Scripts should be vacated, or at least substantially reduced, since Gilead's claim of counterfeiting is subject to dismissal for failure to state a claim for two independent reasons, either one of which may serve as the basis to vacate the Asset Freeze Order. First, the facts alleged in support of Gilead's claim for counterfeiting based on false pedigrees fall exclusively within the purview of the FDA and DSCSA, 21 U.S.C. §§ 360eee to 360eee-4. Second, neither the facts nor the case law support Gilead's claim for counterfeiting that is premised on a false or incorrect pedigree. In view of these circumstances and the prospect of dismissal of these claims, the exceptional provisional relief of an asset freeze, which is available only upon establishing a counterfeiting violation of the Lanham Act, is not appropriate and should be vacated.

A. Gilead's Claim for Counterfeiting Based on False Pedigrees Is Precluded Under DSCSA, 21 U.S.C. § 360eee to 360eee-4 and Renders the Case Subject to Dismissal for Failure to State a Claim

Gilead's counterfeiting claim under the Lanham Act against Scripts is precluded as a matter of law because the facts that support Gilead's Lanham Act claims against Scripts fall within the domain of the FDA, which has exclusive authority to decide claims involving suspect pedigrees/T3s that are used to trace and verify the identity of drugs. *See*, DSCSA, 21 U.S.C. §§ 360eee to 360eee-4.

On November 17, 2013, Congress enacted DSCSA. DSCSA set forth new definitions and requirements for manufacturers, re-packagers, wholesale distributors, and dispensers to facilitate the tracing of product through the pharmaceutical distribution supply chain. In this regard, DSCSA aims to regulate the drug supply chain by implementing a uniform, interoperable system to trace and verify the identity of a drug as it passes through a manufacturer, wholesale

distributor, dispenser, or re-packager in the supply chain. *See e.g., In re Valsartan, Losartan & Irbesartan Prods. Liab. Litig.*, 2020 U.S. Dist. LEXIS 238919, *56 (D.N.J. 2020). DSCSA clearly regulates pedigrees/T3s associated with pharmaceutical drugs. Therefore, a violation of DSCSA's tracing requirements that is premised on creating false or incorrect pedigrees/T3s – which forms the core of Gilead's counterfeiting claim against Scripts – rightfully falls within the purview of the FDA and its oversight of DSCSA, **not** the Lanham Act. In other words, Gilead's claim against Scripts for distributing pharmaceuticals with allegedly false or incorrect pedigrees is governed by the federal law designed to promote public health and safety, i.e., DSCSA.

Although DSCSA includes an explicit preemption clause confirming Congressional intent that DSCSA preempts state law governing the distribution of pharmaceutical drugs, *see*, 21 U.S.C. §360eee-4(b)(1); *Matrix Distribs. v. N.A. of Bds. of Pharm.*, 2020 U.S. Dist. LEXIS 228271 (D.N.J. December 4, 2020), Scripts is not aware of any reported decision holding that competing federal statutes, such as the Lanham Act, are precluded by DSCSA and the FDA's authority. Scripts is also not aware of any cases that sanction Lanham Act cases involving alleged DSCSA violations. Accordingly, it appears as if no specific precedent exists with regard to the interaction between DSCSA and the Lanham Act. However, there are numerous cases dismissing Lanham Act claims on the grounds that they are precluded the Food, Drug and Cosmetic Act (hereinafter the "FDCA"). *See e.g., Amarin Pharma, Inc v. ITC*, 923 F.3d. 959, 967 (Fed. Cir. 2019) (allowing plaintiffs to shoehorn a question of regulatory compliance into the Lanham Act would require judges to make a "preemptive determination of how the FDA would interpret and enforce its own regulations.").

In *Amarin*, the court held that plaintiff's Lanham Act claims were precluded by the FDCA and that the FDA was charged with the administration of FDCA. *Id.* at 966. In *Amarin*,

defendant was accused of using false and misleading labels and advertisements. Plaintiff asserted that labeling the products as “dietary supplements” was literally false because the products could not meet the definition of “dietary supplement” as set forth in Section 201(ff) of the FDCA. *Id.* at 967. Amarin’s complaint relied on these alleged FDCA violations to support key elements of its false advertising claim under the Lanham Act. Accordingly, the Lanham Act claim was dismissed since it was precluded by FDCA. Here, since Gilead’s Lanham Act claim is undeniably premised on a violation of DSCSA based on Scripts’ alleged dealing with false or incorrect pedigrees/T3s, Gilead’s claim will thus likely be precluded and ultimately dismissed as a matter of law just as Amarin’s claim was dismissed since it was precluded by FDCA. Insofar as Gilead’s *ex parte* Asset Freeze Order is tied to its counterfeiting claim that is likely to be precluded, the Court should vacate the Asset Freeze Order.

Cases like *Amarin* suggest that since DSCSA explicitly governs the distribution of products with allegedly false pedigrees that are used to track drugs, the same result of dismissal should apply here with respect to the alleged violation of DSCSA. Accordingly, Gilead should not be permitted to bring claims involving DSCSA violations that are cloaked in a claim of counterfeiting under the Lanham Act.

B. Gilead Cannot Assert a Plausible Claim for Counterfeiting Based Upon a Suspect Pedigree

Even if the Court decides that Gilead’s counterfeiting claim based on false or incorrect pedigrees/T3s should not be precluded by DSCSA, the Court must still vacate the Asset Freeze Order since there is no cognizable claim for counterfeiting under the Lanham Act based on a false pedigree/T3.

An asset freeze order is an extreme provisional remedy. *Grupo Mexicano v. Alliance Bond Fund*, 527 U.S. 308, 144 L.Ed. 2d 319, 119 S.Ct. 1961 (1999). In order to qualify for such

extraordinary relief under the Lanham Act, establishing a claim for mere trademark infringement is entirely insufficient. Rather, Gilead must have established a strong and unquestionable claim for counterfeiting under the Lanham Act to support the Asset Freeze Order that it obtained. *See*, 15 U.S.C. §1116(d). In the instant case against Scripts, Gilead’s claim of counterfeiting under the Lanham Act is premised upon the notion that a suspect pedigree constitutes counterfeiting under the Lanham Act. This is a flawed theory which stands entirely unsupported by any precedent.

Only in extreme cases does trademark infringement rise to the level of counterfeiting. Generally, counterfeiting is considered a first-degree form of infringement that aims to trick a consumer into believing that he or she is getting the genuine article, rather than a “colorable imitation.” *Gucci Am., Inc. v. Guess?, Inc.*, 868 F. Supp. 2d 207, 242 (S.D.N.Y. 2012) (*citing* 4 *McCarthy on Trademarks and Unfair Competition* § 25:10). The Second Circuit has held that unless a defendant engages in exact copying of entire products, trademark counterfeiting claims should be addressed under “traditional infringement principles.” *Gucci Am.*, at 253. As such, courts generally reserve this designation for products that are “stitch-for-stitch *copies* of those of another brand.” *Id.*, at 242. Counterfeiting is a much more grievous violation than lower forms of infringement, as it may expose the infringer to treble or statutory damages and attorney fees, *see* 15 U.S.C. § 1117(b), and it may provide for extraordinary provisional relief like an asset freeze, *see* 15 U.S.C. § 1116(d)(1).

Section 45 of the Lanham Act provides the basic definition of what constitutes a “counterfeit.” A “counterfeit” is defined as a “spurious mark which is identical with, or substantially indistinguishable from a registered mark.” *See*, 15 U.S.C. §1127. “Spurious” is defined as: “Deceptively suggesting an erroneous origin; fake.” Black’s Law Dictionary (10th

ed. 2014). In addition, a “counterfeit mark” is elsewhere defined in the Lanham Act as “a counterfeit of a mark that is registered on the principal register in the [USPTO] for such goods or services sold, offered for sale, or distributed and that is in use...” 15 U.S.C. § 1116(d)(1)(B)(i). Although this portion of the U.S. Code does not specifically use the word “spurious,” the definition set forth in § 1127 is read into § 1116(d)(1)(B)(i). 130 Cong. Rec. H12076, at H12079 (daily ed. Oct. 10, 1984); 7 *McCarthy on Trademarks* Appendix A8 (5th ed.).

Notably, a counterfeit mark is **not**:

[A] mark or designation used on or in connection with goods or services of which the manufacture or producer was, at the time of the manufacture or production in question authorized to use the mark or designation for the type of goods or services so manufactured or produced, by the holder of the right to use such mark or designation.

15 U.S.C. § 1116(d)(1)(B). If a mark is counterfeit, it is always infringing, but the inverse is not necessarily true.

The definition of the term “counterfeit mark” was also discussed in a Joint Statement on Trademark Counterfeiting Legislation. *See*, 130 Cong. Rec. H12076, at H12078 (daily ed. Oct. 10, 1984). As stated in that Joint Statement, the re-sale of goods originally manufactured by the trademark holder, i.e., genuine goods originating from the manufacturer, such as those present in situations of “parallel imports” and “gray market goods” are specifically excluded from consideration as “counterfeit.” *See*, 30 Cong. Rec. H12076, at H12078 (daily ed. Oct. 10, 1984 (“The term ‘counterfeit mark’ in this bill also excludes the marks on so-called ‘parallel imports’ or ‘gray market’ goods – that is, trademarked goods legitimately manufactured and sold overseas and then imported into the United States outside the trademark owner’s desired distribution channels. (*See generally Bell & Howell: Mamiya Co. v. Masel Supply Co.*, 719 F.2d 42 (2d Cir. 1983).”)) This legislative history clearly warns courts against expanding the definition of “counterfeit” – and the extreme provisional remedies that go along with it – far beyond the

traditional understanding that the term “counterfeit” applies to goods that are themselves not genuine because they are not manufactured by the brand-holder.

In all, for counterfeiting liability to attach, the goods themselves need to be non-genuine, meaning that the goods generally need to have been manufactured or originated from an individual or entity other than the owner of the mark. This makes sense since “the purpose of trademark law is not to guarantee genuine trademarks but to guarantee that every item sold under a trademark is the genuine trademarked product, and not a substitute.” *General Electric Company v. Speicher*, 877 F.2d 531, 534 (7th Cir. 1989).

It is rare for a court to entertain a claim of counterfeiting in circumstances where the product itself is genuine. Indeed, Scripts is aware of no reported case, in any jurisdiction, where a claim of counterfeiting under the Lanham Act was established based upon an alleged suspect pedigree, and to Scripts’ knowledge, no such case exists. Nevertheless, Gilead now asks this Court to maintain the most extreme remedy available under the Lanham Act against Scripts, i.e., an *ex parte* Asset Freeze Order, based upon a flawed and newfangled theory of what may constitute a counterfeit under the Lanham Act.

Gilead’s theory of liability for counterfeiting based on a suspect pedigree constitutes an extreme expansion of what a counterfeit is under the Lanham Act. Here, the alleged use of a false or incorrect pedigree/T3 clearly falls outside the scope of the definition of “counterfeit,” since any purported “use”¹ by Scripts of the Gilead marks and/or slogans is in connection with the advertising and sale of authentic Gilead drugs. In other words, since Gilead’s counterfeiting claim against Scripts for false pedigrees/T3s are not premised upon anything other than their use

¹ Scripts does not concede that any references to Gilead marks or slogans on a pedigree/T3 constitute “use” as required under the Lanham Act.

in connection with genuine and authentic Gilead drugs, Gilead's counterfeiting claim will likely fail as a matter of law. As it was made clear in the Joint Statement on Trademark Counterfeiting Legislation, the re-sale of goods originally manufactured by the trademark holder are specifically excluded from consideration as "counterfeit." *See also, United States v. Hanafy*, 302 F.3d 485 (5th Cir. 2002) (affixing a trademark to shipping trays containing parallel goods does not constitute counterfeiting since the goods themselves are entirely genuine and authentic.)

Gilead's contention that false pedigrees constitute counterfeits is also undermined by inconsistent statements from its counsel in correspondence to pharmacies that have purchased Gilead drugs from Scripts. For example, in a letter dated October 25, 2021 from Gilead's counsel to Hoover Drugs LLC, Gilead's counsel states, in relevant part:

We have not yet confirmed whether the Gilead-branded medicines sent to you are counterfeit. However, **we have confirmed that other Gilead-branded medicines-including BIKTARVY® and DESCOVY®-sold by Scripts are counterfeit and could cause harm to patients. Moreover, we have confirmed that numerous Gilead-branded medicines sold by Scripts were accompanied by false pedigree documentation or "T3s."**

(Schurin Decl., ¶ 10, Ex. G) Based on this correspondence, Gilead's counsel does not itself consider false pedigree documentation or "T3s" to render an otherwise genuine bottle of Gilead medication to be counterfeit. If false pedigrees automatically render genuine medication counterfeit, there would be no need to also state that Scripts sold Gilead medication with false pedigree documentation, and the last sentence in the quote above would be entirely unnecessary. Gilead's counsel would have simply stated in his letter that Gilead "has confirmed that other Gilead-branded medicines...sold by scripts are counterfeit and could cause harm to patients."

This is further confirmed by the very next paragraph which begins:

Because there is a chance that the Gilead-branded medicines sold to you by Scripts **are counterfeit and/or are accompanied by falsified pedigree documents**, those medicines should be considered “suspect products” pursuant to the Drug Supply Chain Security Act (DSCSA).

Id. Again, if false pedigree documents render genuine medication counterfeit all on its own, then there would be no need for Gilead’s counsel to stress that the Gilead medication sold by Scripts may be counterfeit **and** are accompanied by falsified pedigree documents. Clearly, Gilead itself understands that a counterfeit constitutes something different than a product accompanied by an incorrect or false pedigree. Therefore, based on its own correspondence sent to pharmacies long after this case commenced, Gilead cannot seriously contend that false pedigree documentation standing alone can support a claim of counterfeiting under the Lanham Act.

The novelty of Gilead’s argument is also evidenced by the lone case it cited in support of its application for *ex parte* relief, *Coty, Inc v. Cosmopolitan Cosmetics, Inc.*, 432 F. Supp. 3d 345, 349, 352-353 (S.D.N.Y. 2020). In *Coty*, the allegations were that the defendant “mutilated” packages of perfume bottles by removing the codes placed there by the manufacturer. In denying defendants’ motion to dismiss, the court held that such a claim could *plausibly* be considered counterfeiting so it would not grant the defendants’ motion to dismiss for failure to state a claim. Notably however, no decision on the merits was ever rendered since the case was ultimately settled on a confidential basis. Moreover, no provisional relief was granted in favor of plaintiffs in *Coty*. Not only did *Coty* not involve a request for extreme relief, it also did not involve pharmaceuticals, false pedigrees or a product that may directly impact public health and safety. Had Gilead been in possession of any better authority, it surely would have cited it in support of its application for the Asset Freeze Order. That none exists demonstrates that the merits of Gilead’s counterfeiting claim against Scripts is far from solid. Insofar as Gilead’s *ex parte* Asset Freeze Order is tied to its counterfeiting claim against Scripts that may very well fail

since the accused products marketed and sold by Scripts are genuine and authentic Gilead drugs, the Court should vacate the Asset Freeze Order.

C. The Two (2) Prior Instances of Tampering and Adulteration Cited in the Second Amended Complaint Do Not Support the Asset Freeze Order

In response to this motion, Gilead will likely raise two independent instances of Script's unintentional sale of adulterated drugs, each of which occurred well before Gilead's application for the *ex parte* Asset Freeze Order. These events were addressed properly with the FDA and with Gilead, as well. (Diamantstein Decl., ¶¶ 23-29) Moreover, if Gilead thought that these two instances warranted urgent action in the form of a seizure or asset freeze, **Gilead would not have waited more than a year to seek the *ex parte* relief that it obtained herein.** Indeed, to the extent that Gilead wishes to rely on Scripts' prior acts that took place long before the acts complained of in this litigation, Gilead's unexcused delay would constitute a valid defense of laches in the Second Circuit, barring the preliminary relief sought by Gilead. *See, Citibank N.A. v. Citytrust*, 756 F.2d 273 (2d Cir. 1985). In addition, if these two instances formed the basis for Gilead's claim of counterfeiting, it could not possibly support freezing over \$ 5 million, since the profit that Scripts earned from the sale of these two bottles are *de minimis*.

IV. GILEAD HAS NOT DEMONSTRATED THAT SCRIPTS WILL DISSIPATE OR SECRETE ITS ASSETS

To justify the continuation of the Asset Freeze Order against Scripts, Gilead also bears a separate and significant burden of proving that Scripts is likely to dissipate or secrete its assets, making collection of a judgment impossible. Indeed, it is Gilead's high burden to demonstrate that "a significant risk that the irreparable harm exists where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied." *Sterling Ornaments Pvt. Ltd. v. Hazel Jewelry Corp.*, 2015 U.S. Dist. LEXIS 77331, at *2 (S.D.N.Y. 2015) (denying request for temporary restraining

order freezing defendants' assets). Thus, even assuming that Gilead has made a *prima facie* case of counterfeiting against Scripts, which is very much disputed, even a *prima facie* case of counterfeiting does not give rise to a presumption that a defendant's cash assets need to be restrained to prevent irreparable harm. And while a *prima facie* case of counterfeiting may in some cases give rise to a presumption of irreparable harm, it does not give rise to a presumption that a defendant's cash assets need to be restrained to prevent irreparable harm. *See e.g., Kebapci v. Tune Core Inc.*, 2016 U.S. Dist. LEXIS 159054, at *4 (E.D.N.Y. 2016).

In this case, if Scripts would have had the opportunity to contest Gilead's application for the asset freeze, it would have been able to establish that all of the available evidence suggests that Scripts is not likely to dissipate or secrete its assets, and on that basis the Asset Freeze would not have been Ordered. For example, Scripts is a stable local entity in business since 2009. (See, Diamantstein Decl. ¶ 2) In the twelve (12) years since it opened its doors, Scripts has operated in the same location. (Diamantstein Decl., ¶ 11) The founder and President of Scripts, Steven Diamantstein lives in Brooklyn with his wife and two small children, (Diamantstein Decl., ¶ 14) and Mr. Diamantstein's father has owned and operated a pharmacy in Brooklyn for more than thirty-five (35) years since April 1986. (Diamantstein Decl., ¶ 13) For nearly a decade, Scripts' has also maintained its monies in a traditional United States bank located in this jurisdiction. (Diamantstein Decl., ¶¶ 17-19) All of these indisputable facts weigh very heavily in favor of Scripts.

On the other hand, in its application for an *ex parte* Asset Freeze Order against Scripts, Gilead submitted virtually no evidence that Scripts is likely to dissipate or secrete its assets. Gilead offered no declarations or other evidence specifically related to Scripts' assets and the likelihood that Scripts would dissipate its assets to avoid a possible judgment. Indeed, Gilead's

Memorandum of Law, dated October 14, 2021, in support of the asset freeze request barely mentions Scripts. Instead, Gilead argues that “Scripts fits the same mold as previously named Distributor Defendants Safe Chain and ProPharma” and that “Scripts should not be given the opportunity to hide or spend its counterfeiting profits.” (Gilead Memorandum of Law, pp. 57-58) Mere conclusory allegations based upon speculation such as this are wholly insufficient to support the contention that Scripts is likely to dissipate its assets or take action to evade judgment. *See e.g., BMaddox Enters, LLC v, Oskouie*, 2017 U.S. Dist. LEXIS 146766, *15 (S.D.N.Y. 2017) (“[A]lthough plaintiff argued that it’s ‘safe to assume,’ or that it is ‘almost certain,’ that defendants would remove assets from the United States, such arguments are little more than speculation and demonstrate, at most, that there is a possibility that defendants would secrete assets to frustrate a judgment.)

In summary, in support of its application for an *ex parte* Asset Freeze Order against Scripts, Gilead presented no evidence from which this Court may infer that any sales proceeds are in fact being secreted or diverted, or that there is even a possibility that Scripts will divert its sales proceeds prior to the conclusion of this litigation. Accordingly, and on this basis alone, the Asset Freeze Order against Scripts should now be vacated. *See, e.g., Haggiag v. Brown*, 728 F. Supp. 286, 291 (S.D.N.Y. 1990) (denying asset freeze where plaintiffs failed to present “any significant evidence of any massive dissipation of assets of the sort which would be required in order for the drastic remedy sought by plaintiffs to be appropriate.”)

Based on a complete record, which was unavailable to Judge Kovner to consider on Gilead’s *ex parte* application, Scripts respectfully submits that Gilead has not and cannot meet its heavy burden of proving that Scripts is likely to dissipate or secrete its assets. Accordingly, Scripts requests that the provisional Asset Freeze Order be vacated in its entirety.

V. THE PUBLIC INTEREST IS NOT SERVED BY MAINTAINING AN ASSET FREEZE OF SCRIPTS' FUNDS

Scripts respectfully submits that the public interest is not benefited by maintaining an Asset Freeze Order against Scripts issued *ex parte* where Gilead's legal claim of "counterfeiting" stands on very shaky ground. In addition, justice is not served when a plaintiff is able to prevail by simply freezing a defendant's financial assets such that it cannot mount a proper defense. Even in cases where the liability is certain or criminal – which is certainly not the case as to Scripts here – courts have still recognized that it is wrong and unfair to deprive a defendant of the means to defend itself through a provisional asset freeze. *See e.g., Adelpia Communs Corp. v. Rigas (In re Adelpia Communs. Corp.)*, 2004 U.S. Dist. LEXIS 19478, *27 (S.D.N.Y. 2004) (Original asset freeze exempted \$15 million to cover civil and criminal defense costs. Then, court affirmed an additional carve-out of \$12.8 million from asset freeze to be used directly for expenses related to defense, e.g., attorney fees, expert and litigation consultants.)

CONCLUSION

For all of the reasons set forth above, the Asset Freeze Order entered against Scripts should be vacated entirely. Alternatively, Scripts respectfully requests that the Asset Freeze Order be modified in accordance with the relief sought herein.

Dated: January 20, 2022
Garden City, New York

Respectfully submitted,

STERN & SCHURIN LLP

By: Richard Schurin
Richard Schurin
rschurin@sternschurin.com
Stanley R. Goodman
sgoodman@sternschurin.com
Steven Stern
sstern@sternschurin.com
Moshe Allweiss
malweiss@sternschurin.com

Attorneys for Defendant
Scripts Wholesale Inc.
595 Stewart Avenue
Suite 510
Garden City, New York 11530
(516) 248-0300